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10/587,993	06/13/2007	Deborah Addison	101713-5037	1396
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MORGAN, LEWIS & BOCKIUS LLP 1701 MARKET STREET PHILADELPHIA, PA 19103-2921			ORWIG, KEVIN S	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,993	Applicant(s) ADDISON ET AL.
	Examiner Kevin S. Orwig	Art Unit 1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).

Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 April 2009.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-8 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-8 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date _____

5) Notice of Informal Patent Application
6) Other: _____

DETAILED ACTION

The amendments and arguments filed Apr. 23, 2009 are acknowledged and have been fully considered. Claims 1-8 are now pending. Claims 9 and 10 are cancelled; no claims are amended.

OBJECTIONS/REJECTIONS MAINTAINED

The rejection of claims 1-8 under 35 U.S.C. 103(a) is maintained as discussed below.

Claim Rejections - 35 USC § 103 (Maintained)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over CHEONG (U.S. 6,326,410; Issued Dec. 4, 2001; 2nd Reference on IDS dated Aug. 2, 2007) in view of WEBSTER (U.S. 4,664,662; Issued May, 12, 1987).

1. Cheong discloses polyurethane foams useful as wound dressings and methods to make the same (abstract; col. 5, lines 15-36). Cheong teaches a method of forming the polyurethane foam comprising mixing 1 part by weight of an isocyanate-capped prepolymer having from 0.5 to 1.2 meq NCO groups/gm with 0.509 to 1.18 parts by weight of water in the presence of from 0.05 to 0.4 parts by weight of a C1 to C3 monohydric alcohol (col. 5, lines 18-23; claims 1-2). Cheong also teaches drying the foamed product (col. 5, lines 25-27). Cheong does not *explicitly* teach treating the foamed product with a dispersion of therapeutic agent prior to drying.

2. However, Cheong contemplates such treatment by teaching that "the foams of the invention may also include topical medicaments and antiseptics...as well as other therapeutically useful additives" (col. 3, line 65 to col. 4, line 3). Furthermore, treatment of similar polyurethane foams with therapeutic agents is well-known in the art. For example, Webster teaches polyurethane foam wound dressings that may contain

therapeutic agents (abstract; col. 7, line 61 to col. 8, line 7; claim 11). Webster teaches that the physiologically active component may be incorporated into the foam prior to use by soaking (i.e. treating) it in a solution of the components (col. 8, lines 8-13).

3. In light of these teachings, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to treat the polyurethane foams of Cheong with a dispersion of a therapeutic agent, then drying the treated product as taught by Cheong, to provide a wound dressing material comprising a therapeutically active agent, reading on claim 1. One would have been motivated to do so since both Cheong and Webster teach that it is useful to include such agents on polyurethane wound dressing materials, as would be clear to the ordinary artisan. Therefore if an artisan wanted to produce a medicated foam dressing material, one would have been motivated to treat the polyurethane foams of Cheong with a dispersion of a therapeutic agent per the teachings of Webster.

4. Regarding claim 2, Cheong teaches that methanol is a particularly preferred monohydric alcohol for use in the method of forming the foams (col. 3, lines 42-48), reading on claim 2.

5. Regarding claim 3, Cheong teaches that the prepolymer of the invention is preferably an isocyanate-capped polyether such as an ethyleneoxy/propyleneoxy copolymer (col. 2, lines 44-48), reading on instant claims 3 and 4.

6. Regarding claim 5, Cheong teaches a method of forming the polyurethane foam comprising mixing 1 part by weight of an isocyanate-capped prepolymer having from 0.5 to 1.2 meq NCO groups/gm with 0.509 to 1.18 parts by weight of water (col. 5, lines 18-

23; claim 1). Additionally, Cheong teaches mixing the isocyanate-capped prepolymer with 0.6 to 0.9 parts by weight of water (claim 7), reading on claim 5.

7. Regarding claim 6, Cheong teaches a method of forming the polyurethane foam comprising mixing 1 part by weight of an isocyanate-capped prepolymer having from 0.5 to 1.2 meq NCO groups/gm with 0.6 to parts by weight of water in the presence of from 0.6 to 0.4 parts by weight of a C1 to C3 monohydric alcohol (col. 5, lines 18-23; claims 1-2). Additionally, Cheong teaches mixing these components in the presence of from 0.1 to 0.25 parts by weight of methanol or from 0.1 to 0.3 parts by weight of ethanol (claims 8 and 9), reading on claim 6.

8. Regarding claim 7, Cheong teaches drying the polyurethane foam product (col. 5, lines 25-27) as discussed above. Cheong does not explicitly teach treating the foamed product with a dispersion of therapeutic agent prior to drying, and thus does not teach an *extra* drying step.

9. However, as discussed above Webster teaches that physiologically active components may be incorporated into the foam prior to use by soaking (i.e. treating) it in a solution of the components (col. 8, lines 8-13). Webster teaches that the physiologically active component may be incorporated just prior to use (col. 8, lines 8-13). Webster also teaches drying the foam in an oven. For instance, Example 1 demonstrates the preparation of a polyurethane dressing material that is not treated with an active agent. Thus, one of ordinary skill in the art would recognize that the foams of Webster would have been dried prior to soaking them in a solution of the active agent(s). Webster teaches soaking the dried foam in a solution of an active

agent followed by drying (col. 8, lines 13-17). Therefore, in combination with Cheong, Webster teaches the method to make the foams of instant claim 6 including the step of drying the foam prior to treatment with an active agent. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to dry the polyurethane foams again after soaking the foam in a solution of the active agent as taught by Webster. The ordinary artisan would have been motivated to do so since the artisan would readily envisage advantages of drying the foam after such treatment, for example for long-term storage and ease of packaging the foams/wound dressings. Thus, the combined teachings of Cheong and Webster read on claim 7.

10. Regarding claim 8, Webster teaches that the foams may be treated with a 5% w/v solution of chlorhexidine gluconate (col. 8, lines 13-17). The ordinary artisan would recognize that this solution is an aqueous solution since Webster teaches that this soaking treatment is preferred for those physiologically active components that are soluble in water (col. 8, lines 11-13), and chlorhexidine gluconate is water soluble. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to treat the polyurethane foams of Cheong with an aqueous solution of agent having a concentration of from 1 to 20% wt per the teachings of Webster, reading on claim 8. The ordinary artisan would have had a reasonable expectation of success in doing so since Cheong suggests such a treatment as discussed above, and since Webster exemplifies such a treatment with an active agent in this concentration range.

A reference is good not only for what it teaches by direct anticipation but also for what one of ordinary skill in the art might reasonably infer from the teachings. (*In re Opprecht* 12 USPQ 2d 1235, 1236 (Fed Cir. 1989); *In re Bode* 193 USPQ 12 (CCPA) 1976). In light of the forgoing discussion, the examiner concludes that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a). From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, in the absence of evidence to the contrary, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Response to Arguments

Applicants' arguments have been fully considered but are not persuasive. Applicants argue that the cited references do not teach treating the foamed product with active agent and drying the treated product. Applicants further argue that Webster cannot cure the deficiencies of Cheong (response, p. 4).

Cheong teaches that "the foams of the invention may also include topical medicaments and antiseptics...as well as other therapeutically useful additives" (col. 3, line 65 to col. 4, line 3). Cheong also teaches drying the foamed product (col. 5, lines 25-27). This teaching alone would be sufficient to guide a skilled artisan to the instant invention. While Cheong is silent to exactly when the active agent(s) are added, there are only two possibilities. Either the active agents are added before or after drying the foams as taught by Cheong. A skilled artisan would readily envision both possibilities,

even without the teachings of Webster.

However, Webster clearly provides all the teaching and motivation necessary to arrive at the instantly claimed invention. Based on Webster's teachings (discussed *supra*), one of ordinary skill in the art would recognize that the foams of Webster would have been dried prior to soaking them in a solution of the active agent(s). Webster teaches soaking the dried foam in a solution of an active agent followed by drying (col. 8, lines 13-17). Therefore, in combination with Cheong, Webster teaches the method to make the foams of instant claim 6 including the step of drying the foam prior to treatment with an active agent. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to dry the polyurethane foams again after soaking the foam in a solution of the active agent as taught by Webster. The ordinary artisan would have been motivated to do so since the artisan would readily envisage advantages of drying the foam after such treatment, for example for long-term storage and ease of packaging the foams/wound dressings. Thus, to a skilled artisan, the combined teachings of Cheong and Webster clearly suggest all the limitations of the instant method.

Applicants' arguments completely disregard the skill of the ordinary artisan. Applicants' position is that a skilled artisan could never decide when to add an active agent to a wound contact material, even with suggestion to add the active agent at various times during and after manufacture of the material, which is provided by both Cheong and Webster. The MPEP states, "A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton." KSR, 550 U.S. 82 USPQ2d at 1397.

"[I]n many cases a person of ordinary skill will be able to fit the teachings of multiple patents together like pieces of a puzzle." *Id.* Office personnel may also take into account "the inferences and creative steps that a person of ordinary skill in the art would employ." *Id.* at 82 USPQ2d at 1396. In addition to the factors above, Office personnel may rely on their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art. The Federal Circuit has stated that examiners and administrative patent judges on the Board are "persons of scientific competence in the fields in which they work" and that their findings are "informed by their scientific knowledge, as to the meaning of prior art references to persons of ordinary skill in the art." *In re Berg*, 320 F.3d 1310, 1315, 65 USPQ2d 2003, 2007 (Fed. Cir. 2003).

Moreover, the term "drying" is not defined in the instant specification. Thus, the term can be construed broadly. Regarding the teachings of Webster, the mere act of removing the foam from the treatment solution is inherently drying the foam since excess treatment solution will drip off the foam and since some evaporation of the aqueous solution will occur between removal of the foam from the treatment solution and placement on the skin/wound. Further drying will occur while the foam is in use (i.e. on the wound of the user), and such drying is not excluded by the instant claims.

Applicants further argue that the loading of the active agent in the instant invention occurs before the product has been packaged and shipped for use (response, p. 4). In response to applicant's argument that the references fail to show certain features of applicants' invention, it is noted that the features upon which applicant relies (i.e., that loading of the active agent occurs before packaging and shipping the product)

are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Applicants also allege unexpected sustained release behavior of the instantly claimed foams (response, p. 4-5). Applicants point to Procedure 1 (in Example 2) and Figure 1 to support this allegation.

Applicants have not provided sufficient evidence to support this allegation. At a minimum, applicants have not shown that the amount of CHG added to the mixed foam was the same as that added to the dried foam to which CHG was applied. Such equivalence is not apparent from Procedure 1 or Figure 1. In fact, if it was the foams prepared in Example 1 that were used for the comparison, as may be presumed based on the description of Examples 1 and 2, it is apparent that more CHG was added to the foams which were immersed in CHG solution (10% w/v CHG solution was used) than was added to the foams in which the CHG was incorporated by mixing (2% w/v CHG solution was used). Thus, the alleged unexpected results can hardly be considered "surprising" or "unexpected" to one of skill in the art. Since more CHG was added to the immersed foams, it is not surprising that they contained more CHG, and equally not surprising that they would release this *greater amount* of CHG over a longer period of time.

Moreover, even if, *in arguendo*, applicants' allegation were sufficiently demonstrated, the instant claims recite no such limitations regarding these results, and are not commensurate in scope with the same. Thus, applicants' assertion of

unexpected results is not persuasive.

The claims stand properly rejected over Cheong and Webster.

Summary/Conclusion

Claims 1-8 are rejected; claims 9 and 10 are cancelled.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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KSO

/David J Blanchard/
Primary Examiner, Art Unit 1643